J. Stone
7505C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JAN 24 1997

MEMORANDUM

SUBJECT: PP# 6F04748. Difenoconazole (Dividend) in or on Barley. Amendment of 12/9/96. Revised Sections B & F. MRID# none. Barcode D232351. Case 287954. Chemical 128847.

FROM: G.F. Kramer, Ph.D., Chemist
Tolerance Petition Team I
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: E.T. Haeberer, Acting Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: C. Eiden/D. McCall
Registration Section, RCAB
Health Effects Division (7509C)

CIBA-GEIGY Corporation has proposed tolerances for residues of the fungicide difenoconazole ([(2S,4R)/(2R,4S)]/[(2R,4R)/(2S,4S)]1-{2-[4-(4-chlorophenoxy)-2-chlorophenyl]-4-methyl-1,3-dioxolan-2-yl-methyl}-1*H*-1,2,4-triazole) in/on barley RACs.

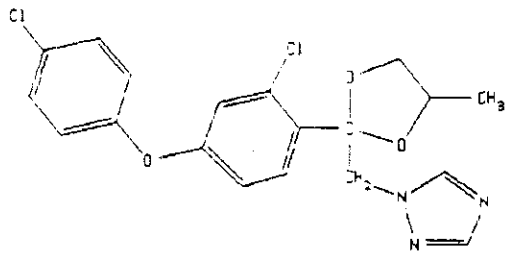
The proposed tolerances, expressed as parent compound only, are:

Barley, forage -- 0.05 ppm		Barley, hay --	0.05 ppm
Barley, straw -- 0.05 ppm		Barley, grain --	0.01 ppm

Tolerances with an expiration date of 12/31/98 are established for residues of difenoconazole *per se* in/on wheat and animal RACs under 40 CFR § 180.475(a). Tolerances for residues of difenoconazole in/on imported barley, rye and wheat grain and animal RACs are established under 40 CFR § 180.475(c) and range from 0.01-0.1 ppm.

The current amendment addresses deficiencies identified in CBTS's previous review (Memo, G. Kramer 9/23/96: D228403).

The structure of difenoconazole is shown below:



Difenoconazole

Executive Summary of Chemistry Deficiencies

- Complete interference study or selective confirmatory technique for analytical method for plants.
- Additional storage stability data.
- Revised Section F.
- FQPA compliance determination.

RECOMMENDATIONS

CBTS recommends against the proposed tolerance for difenoconazole in/on barley RACs for reasons detailed in Conclusions 1a, 1b, 2, 4, and 5, below.

CONCLUSIONS

1a. The petitioner has referenced a previously submitted interference study (MRID# 428065-05). None of the tested pesticides interfered with difenoconazole. However, there are several pesticides for which tolerances are established or proposed for barley and were not tested (imidacloprid, tebuconazole, methoprene, triasulfuron, imazethabenz, prosulfuron, tralkoxydim, pendimethalin, fluroxypyr, fenoxaprop-ethyl, isoxaben, and flusilazole). The petitioner should provide the results of

interference testing for these compounds.

1b. A conclusion on the adequacy of the analytical method for enforcement of the proposed tolerances will be withheld pending demonstration of method specificity (interference study or selective confirmatory technique).

2. The RAC samples from the field residue studies were stored for a maximum of 23 months. Difenoconazole has been previously shown to be stable in potatoes and tomatoes for up to 2 years of storage and in wheat forage and bananas for 1 year. Further studies are needed to demonstrate storage stability in the RACs wheat (or barley) grain and straw (PP#2F4107; Memo, G. Kramer 6/16/94).

3. The previously requested revisions to Sections B & F have been made.

4. The revised Section F submitted by the petitioner also includes a proposed tolerance of 0.01 ppm for barley grain. As a tolerance for residues of difenoconazole in/on barley grain of 0.1 ppm is established under 40 CFR § 180.475(c), the tolerance for barley grain proposed in this petition should be withdrawn. A revised Section F is required.

5. HED notes that the Food Quality Protection Act of 1996 has amended and strengthened the standard for establishing tolerances under the FFDCA. OPP is still assessing the full impact of this change in the law on the tolerance-setting process and plans to issue guidelines concerning the establishment of tolerances under the amended statute. All tolerance petitions have to meet the requirements of the FFDCA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 6b (from Memo, G. Kramer 9/23/96)

6b. As no confirmatory method is available, the specificity of the analytical enforcement method should be demonstrated by performing an interference study with all pesticides for which tolerances are established on barley and oats. Alternatively, the petitioner may propose a selective (i.e., GC/MS) confirmatory technique.

Petitioner's Response: The original submission of Method AG-575B (MRID# 428065-04) included an interference study.

CBTS's Conclusion: The original submission of Method AG-575B does not contain an interference study, but does contain a reference to

a previously submitted study. CBTS has re-examined the original interference study (MRID# 428065-05). None of the tested pesticides interfered with difenoconazole. However, there are several pesticides for which tolerances are established or proposed for barley and were not tested (imidacloprid, tebuconazole, methoprene, triasulfuron, imazethabenz, prosulfuron, tralkoxydim, pendimethalin, fluroxypyr, fenoxaprop-ethyl, isoxaben, and flusilazole). The petitioner should provide the results of interference testing for these compounds. This deficiency remains outstanding.

Deficiency - Conclusion 6c (from Memo, G. Kramer 9/23/96)

6c. CBTS concludes that Method AG-575B is adequate for data gathering purposes. A conclusion on the adequacy of the method for enforcement of the proposed tolerances will be withheld pending demonstration of method specificity (interference study or selective confirmatory technique).

Petitioner's Response: see above

CBTS's Conclusion: The requested information has not been provided. This deficiency remains outstanding.

Deficiency - Conclusion 7 (from Memo, G. Kramer 9/23/96)

7. The RAC samples from the field residue studies were stored for a maximum of 23 months. Difenoconazole has been previously shown to be stable in potatoes and tomatoes for up to 2 years of storage and in wheat forage and bananas for 1 year (Memos, R. Lascola 10/26/92 and G. Kramer 3/30/94 & 2/23/96). Further studies are needed to demonstrate storage stability in the RACs wheat (or barley) grain and straw (PP#2F4107; Memo, G. Kramer 6/16/94). The petitioner reports that a 2-year storage stability study on wheat RACs is in progress.

Petitioner's Response: A 2-year storage stability study on wheat RACs is in progress.

CBTS's Conclusion: The requested information has not been provided. This deficiency remains outstanding.

Deficiency - Conclusions 9a & 9b (from Memo, G. Kramer 9/23/96)

9a. No residue data were submitted for triticale. However, 40 CFR § 180.1(h) specifies that wheat tolerances also include triticale. As wheat tolerances for difenoconazole are also established, triticale may be added to the Dividend labels without submission of additional data. However, the petitioner has proposed a shorter PHI for triticale forage (30 days) than is currently established for wheat forage (55 days). Residue data for triticale forage should be provided to support the proposed 30-day PHI or the Dividend labels modified to specify a 55-day PHI for triticale forage.

9b. CBTS notes that the conditions applied to the wheat registration will also apply to the triticale registration. Section F should be modified by removal of the proposed triticale tolerances.

Petitioner's Response: Submission of a revised Section F in which the proposed tolerances for triticale were withdrawn and a revised Section B in which the PHI for triticale was revised to 55 days.

CBTS's Conclusion: The requested revisions to Sections B & F have been made. This deficiency is now resolved.

Deficiency - Conclusion 10 (from Memo, G. Kramer 9/23/96)

10. No residue data were submitted for oats. The petitioner claims that the wheat and barley data may be translated to oats. Based on the presence of detectable residues in some of the wheat and barley field trials reflecting seed treatment applications at roughly the rate proposed in this petition, CBTS is not willing to waive the need for oat field trials. However, CBTS will take into account the data on wheat and barley when determining the number of trials needed for oats. Provided residues in oat RAC's are less than the LOQ at all sites, the number of trials for oats may be reduced from the usually required 12 (for a use with <LOQ residues) to 6.

Petitioner's Response: Submission of a revised Section F in which the proposed tolerances for oat RACs were withdrawn and a revised Section B in which the use on oats was removed.

CBTS's Conclusion: As the proposed tolerances for oat RACs have been withdrawn, this deficiency is no longer germane.

Deficiency - Conclusion 14 (from Memo, G. Kramer 9/23/96)

14. HED notes that the Food Quality Protection Act of 1996 has amended and strengthened the standard for establishing tolerances under the FFDCA. OPP is still assessing the full impact of this change in the law on the tolerance-setting process and plans to issue guidelines concerning the establishment of tolerances under the amended statute. All tolerance petitions have to meet the requirements of the FFDCA as amended by the FQPA and OPP may require additional data to determine if the terms of the amended statute are met.

Petitioner's Response: Submission of an FQPA document.

CBTS's Conclusion: The determination of compliance with FQPA is under the purview of RCAB. CBTS thus defers the review of this document to RCAB. This deficiency remains outstanding.

Other Considerations

The revised Section F submitted by the petitioner includes a

proposed tolerance of 0.01 ppm for barley grain. As a tolerance for residues of difenoconazole in/on barley grain of 0.1 ppm is established under 40 CFR § 180.475(c), the tolerance for barley grain proposed in this petition should be withdrawn. A revised Section F is required.

cc: PP#6F04748, Kramer, R.F., Circ., J. Stone/C. Giles-Parker (RD, 7505C)
RDI: TPT1 (1/16/97), R.A. Loranger (1/23/97), E.T. Haeberer (1/24/97)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

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